

In re Patent Application of:

**AGRAMA**

Serial No. **10/615,963**

Filing Date: **JULY 9, 2003**

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#### REMARKS

Applicant would like to thank the Examiner for the thorough examination of the present application. The Applicant notes that the Examiner did not initial the last two prior art references on the information disclosure sheet. The Applicant requests that the Examiner initial these references, one of which is currently being used to reject the pending claims.

The independent claims have been amended to more clearly define the present invention over the cited prior art references. The claim amendments and arguments supporting patentability of the claims are presented in detail below.

#### I. The Claimed Invention

The present invention, as recited in amended independent Claim 1, for example, is directed to a method for reducing pressure damage to skin of a person. The method comprises determining at least one location on the person susceptible to pressure damage, and adhesively securing a skin protective device to the at least one location. The skin protective device comprises a substrate having an inner surface and an outer surface, an adhesive layer substantially covering the inner surface, and at least one fluid-filled cell on the outer surface.

Independent Claim 1 has been amended to further recite that the substrate is devoid of an opening therethrough. In addition, independent Claim 1 has been amended to recite that the adhesive layer substantially covering the inner surface is for adhesively securing the substrate to the skin of the person.

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The skin protective device in accordance with the claimed invention advantageously reduces pressure damage to the skin of a person. Pressure damage occurs when the skin breaks down as a result of continuous pressure, thus forming open sores. Areas most commonly affected include the skin over the heel, ankle bones, tailbone, hip bones and the sacral area of the lower back.

The skin protective device distributes the pressure being applied to the skin of the person over a surface area of the substrate. Since the surface area of the substrate is devoid of an opening therethrough, the pressure may be uniformly distributed across the skin in contact with an inner surface of the substrate. In addition, the at least one fluid-filled cell is on the outer surface of the substrate, and advantageously increases the area over which the pressure is distributed, thereby reducing the effects of the pressure. Another benefit is that the skin protective device may be easily applied to the skin and is held in position via the adhesive layer without causing unnecessary discomfort to the person.

Independent device Claim 14 has been amended similar to independent method Claim 1, and is directed to the skin protective device (as recited in Claim 1) for reducing pressure damage to the skin of a person. Independent device Claim 14 further recites a removable layer on the adhesive layer to protect the adhesive layer prior to application to the skin of the person.

Independent device Claim 25 is similar to independent device Claim 14, but further recites that the at least one fluid-filled cell comprises a plurality of fluid-

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filled cells on the outer surface of the substrate to define an exposed outermost surface for the skin protective device to cushion the skin of the person.

Independent device Claim 31 is similar to independent device Claim 14, but does not recite the substrate. Instead, an outer surface of the adhesive layer substantially covers the inner surface of the at least one fluid-filled cell.

## **II. Claims 31-36 Are Supported By The Specification**

The Examiner objected to the specification based upon the position that new matter was added via the Preliminary Amendment filed after the specification was filed. As a result, the Examiner rejected Claims 31-36 as not being supported by the specification.

In particular, the Examiner states that the specification as originally filed does not provide for "the outer surface of said adhesive layer substantially covering the inner surface of said at least one fluid-filled cell" as recited in independent Claim 31.

The Applicant respectfully submits that applying an adhesive layer to the fluid-filled cell instead of to the inner surface of a substrate, wherein the fluid-filled cell is on the outer surface of the substrate, is a modification to the present invention that is included within the scope of the claims. There are several references within the specification that the invention is not limited by the illustrated embodiments. For instance, page 6, lines 11-17 in the specification provides:

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"This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art."

Reference is also directed to the page 10, lines 12-20 in the specification, which provides:

"Many modifications and other embodiments of the invention will come to the mind of one skilled in the art having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed, and that modifications and embodiments are intended to be included within the scope of the appended claims."

Moreover, U.S. Patent No. 5,944,683 cited in the background section of the specification discloses therein in FIG. 5a an adhesive layer applied directly to a pressure resilient cushion. Consequently, the above quoted language from the specification, in addition to the prior art cited by the Applicant, permits one skilled in the art to realize that the Applicant had possession of the claimed invention at the time the application was filed.

In other words, the specification supports the skin protective device not including a substrate, or alternatively, the substrate is integrated with the adhesive layer. Consequently, Claims 31-36 contain subject matter that is supported by the specification.

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### **III. The Claims Are Patentable**

The Examiner rejected independent Claims 1, 14, 25 and 31 as being anticipated by the Maiwald patent (U.S. Patent No. 6,096,943). Referring to FIGS. 1-7 in the Maiwald patent, the illustrated skin wound protector **14** protects a wound **12** from contact with solid objects and includes a substantially planar peripheral region **18** having top and bottom sides with adhesive **17** on the bottom for securing the protector to an area surrounding the wound.

A deformable interior region **16** rises above the peripheral region **18** top side to form a hollow cavity such that, when the adhesive **17** is secured to the area surrounding the wound, the wound resides within the cavity and is isolated from contact by solid objects. The skin wound protector **14** can be of unitary or multiple-piece construction and can be fabricated out of air-permeable, air-impermeable, clear or opaque plastic. The hollow cavity is generally dome-shaped and can further contain a medicating fluid **13** for treating the wound.

The Examiner has taken the position that the skin wound protector **14** inherently teaches a method for reducing pressure damage to the skin of a person as in the claimed invention. The Examiner characterized the substantially planar peripheral region **18** as a substrate, wherein the adhesive **17** substantially covers the inner surface thereof.

One distinction in the Maiwald patent is that the planar peripheral region **18** has an opening therein so that the skin wound protector **14** forms a hollow cavity over the area of

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the skin to be protected. As a result, pressure is may not be uniformly applied to this area of the skin under the hollow cavity. Instead, pressure is applied to the skin in contact with the planar peripheral region **18** so that the wound has reduced pressure being applied thereto.

In sharp contrast, the substrate in the skin protective device in the claimed invention does not have an opening therein, and consequently, does not form a hollow cavity over the area of the skin to be protected. This distinction has been highlighted by amending independent Claim 1 to recite that the substrate in the skin protective device is devoid of an opening therethrough.

Moreover, since the adhesive layer in the claimed invention "substantially" covers the inner surface of the substrate for adhesively securing the skin protective device to the skin that is susceptible to pressure damage, the skin that is being protected comes in contact with the adhesive layer. In the Maiwald patent, the adhesive **17** is on the planar peripheral region **18**, and is adjacent the wound that is being protected by the skin wound protector **14**. In other words, the adhesive **17** does not come in contact with the skin that is being protected.

Yet another distinction is that the skin wound protector **14** in the Maiwald patent serves a different purpose than the skin protective device in the claimed invention. In Maiwald, the skin wound protector **14** is for protecting a wound to the skin, after the wound has occurred. If it were not for the wound, the skin wound protector **14** would never be applied to the skin. In sharp contrast, the skin protective device in the claimed invention is for reducing pressure damage to the

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skin of a person. In other words, the skin protective device in the claimed invention is applied before a pressure sore develops.

Accordingly, it is submitted that amended independent Claim 1 is patentable over the Maiwald patent. Amended independent Claims 14, 25 and 31 are similar to amended independent Claim 1. Therefore, it is submitted that these claims are also patentable over the Maiwald patent. In view of the patentability of amended independent Claims 1, 14, 25 and 31, it is submitted that their dependent claims, which recite yet further distinguishing features of the invention, are also patentable. These dependent claims require no further discussion herein.

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**CONCLUSION**

In view of the amendments to the claims and the arguments provided herein, it is submitted that all the claims are patentable. Accordingly, a Notice of Allowance is requested in due course. Should any minor informalities need to be addressed, the Examiner is encouraged to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,



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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS AMENDMENT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, on this 11<sup>th</sup> day of January, 2006.

